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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

RANDY SMITH, Individually and on Behalf of All Others Similarly Situated,	:	Civil Action No.: 17-8945(MAS)(DEA)
Plaintiff,	:	CLASS ACTION
v.	:	
ANTARES PHARMA, INC., ROBERT F. APPLE and FRED M. POWELL,	:	**CONSOLIDATED AMENDED CLASS ACTION COMPLAINT**
Defendants.	:	**JURY TRIAL DEMANDED**

Lead Plaintiff Serghei Lungu ("Plaintiff"), individually and on behalf of all other persons similarly situated, by his undersigned attorneys, for his consolidated complaint against Defendants, alleges the following based upon personal knowledge as to himself and his own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through its attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Antares Pharma, Inc. ("Antares" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet.

Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased or otherwise acquired Antares common stock between December 21, 2016 and October 12, 2017, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Antares develops, manufactures and commercializes therapeutic products using its drug delivery systems. Its subcutaneous injection technology platforms include the VIBEX disposable pressure-assisted auto injector system suitable for branded and generic injectable drugs in unit dose containers, reusable needle-free spring-action injector devices, and disposable multi-use pen injectors for use with cartridges. The Company distributes its needle-free injector systems in various countries. Antares also conducts research and development with transdermal gel products and has several products in clinical evaluation with partners.

3. Founded in 1979, the Company is headquartered in Ewing Township, New Jersey. Antares's common stock trades on the NASDAQ Capital Market ("NASDAQ") under the ticker symbol "ATRS."

4. At all relevant times, Antares's product Xyosted (known until May 2017 as QuickShot Testosterone, or "QST") was the Company's lead product candidate. Xyosted is an auto injector product designed for testosterone replacement therapy ("TRT").

5. While injectable testosterone has been commercially available in the U.S. for almost 70 years, Antares's auto injector was promoted as a painless and efficient injection.

6. Antares announced its submission of a New Drug Application ("NDA") for Xyosted to the U.S. Food and Drug Administration ("FDA") on December 21, 2016. Shortly thereafter, Defendants announced that the target date for completion of the FDA's review of the Xyosted NDA would be October 20, 2017.

7. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operational and compliance policies. Among other things, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the risk of suicide with Xyosted was far greater than with any other currently marketed TRT; (ii) multiple suicides had occurred during the QST clinical studies, as opposed to the single instance disclosed to investors; (iii) Xyosted's pivotal trial showed a high risk of hypertension; (iv) Antares had provided insufficient data to the FDA in connection with its NDA for Xyosted; (v) accordingly, Antares had overstated the approval prospects for Xyosted; and (vi) as a result of the foregoing, Antares's public statements regarding Xyosted were materially false and misleading during the Class Period.

8. Antares, which had never turned a profit, incurred debt and engaged in a risky regulatory shortcut in a bid to attain rapid profitability for the Company, after having been threatened with delisting from the NASDAQ prior to the start of the Class Period.

9. In their race for approval and profit, Defendants downplayed adverse events involving suicide and high blood pressure that occurred in Xyosted's clinical trials. That these issues are more present in Xyosted than in other TRTs on the market is highly relevant because

Antares did not include a control arm in its clinical studies of Xyosted. Therefore, the FDA evaluated Xyosted based on its experience with numerous other TRTs.

10. Defendants rushed to perform a quick extension study in an attempt to influence the FDA – despite knowing of the serious adverse events described above, as well as the FDA's then-current requirement that new drug sponsors conduct blood pressure studies.

11. Although a single suicide had been disclosed – which was already alarming in light of the relatively small study population – Defendants failed to disclose the presence of additional suicides in Antares's pivotal clinical study.

12. While the threat to the Xyosted NDA posed by the incidents of increased blood pressure was raised and discussed internally at Antares, increases in hypertension were not disclosed to investors in the announcement of final study results for Xyosted's pivotal trial, nor indeed at any time prior to the FDA's initial rejection of the Xyosted NDA.

13. During the Class Period, Defendants treated approval by the FDA as synonymous with profitability, even though the increase in hypertension associated with Xyosted risked rejection of the NDA, or black box labeling that would have a negative impact on doctors prescribing Xyosted. The materialization of either risk would negatively impact sales.

14. Because the FDA is statutorily-prohibited from discussing an active NDA outside of an advisory committee – which did not occur here, Defendants were the primary source that investors relied upon concerning the Xyosted NDA.

15. After the market had closed on October 12, 2017, Antares revealed to investors that the Company had received a letter from the FDA on October 11, 2017, that "identified deficiencies that preclude the continuation of the discussion of labeling and post marketing requirements/commitments" for Xyosted. (This was followed up a week later with a Complete

Response Letter ("CRL") from the FDA rejecting "the NDA in its present form" as the FDA was concerned that Xyosted "could cause a clinically meaningful increase in blood pressure" as well as "the occurrence of depression and suicidality.")

16. On the revelation of the October 11, 2017 FDA letter, Antares common stock fell 37.80%, or $1.41 per share, and closed at $2.32 per share on October 13, 2017.

17. Just days earlier, on October 9, 2017, Antares's Chairman of the Board, Leonard S. Jacob, sold hundreds of thousands of shares from his personal portfolio, reaping a windfall of nearly $1 million.

18. Antares eventually resubmitted the NDA for Xyosted, and on October 1, 2018, the Company announced that the FDA had approved the drug, but required a black box warning describing the increased blood pressure that could lead to major adverse cardiovascular events, as well as a separate section on the "Risk of Depression and Suicide" under "Warnings and Precautions." Another concealed risk hidden by Defendants' non-disclosures had now materialized.

19. On the heels of the revelation of approval with the requirement of a black box warning and risk of depression and suicide, Antares common stock fell 3%, or $0.10 per share, and closed at $3.16 per share on October 1, 2018.

20. Upon the disclosures and materialization of the risks of Defendants' wrongful acts and omissions, and the accompanying precipitous decline in the market value of the Company's securities, Plaintiff and other Class members suffered significant losses and damages.

JURISDICTION AND VENUE

21. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

22. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and Section 27 of the Exchange Act.

23. Venue is proper in this Judicial District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b). Antares's principal executive offices are located within this Judicial District.

24. In connection with the acts, conduct and other wrongs alleged in this Complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

25. Plaintiff, as set forth in the Certification submitted in conjunction with his lead plaintiff application (*see* ECF No. 9-2), acquired Antares securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures and/or materialization of the risks.

26. Defendant Antares is incorporated in Delaware, with principal executive offices located at 100 Princeton South, Suite 300, Ewing, New Jersey 08628. Antares's shares trade on the NASDAQ under the ticker symbol "ATRS."

27. Defendant Robert F. Apple ("Apple") has served at all relevant times as the Company's Chief Executive Officer ("CEO"), President and Director.

28. Defendant Fred M. Powell ("Powell") has served at all relevant times as the Company's Chief Financial Officer ("CFO") and Senior Vice President.

29. Defendant Leonard S. Jacob ("Jacob") has served at all relevant times as the Company's Chairman of the Board ("COB"). On October 9, 2017, three days before the risks concealed by Defendants began to materialize, COB Jacob sold 200,000 shares of Antares stock at $4.0521 and an additional 30,000 shares of Antares stock at $4.05 for a total of $931,920.

30. The defendants referenced above in ¶¶27-29 are sometimes referred to herein as the "Individual Defendants."

SUBSTANTIVE ALLEGATIONS

Background

The New Drug Approval Process

a. General Protocols

31. In the United States, pharmaceutical development and marketing is regulated by the FDA. The modern regulatory regime was enacted in 1962, after Thalidomide, a sleeping pill, caused birth defects in thousands of babies. In reaction to this tragedy, Congress passed the Kefauver-Harris Amendments to the Food, Drug and Cosmetic Act requiring that any company that wanted to market a pharmaceutical product in the United States (in industry parlance, a "sponsor") had to obtain prior approval from the FDA, and that the approval had to be based upon substantial scientific evidence demonstrating that the product was safe and effective for its intended use in humans.

32. The Food, Drug and Cosmetic Act, as amended, requires the Commissioner of the FDA to refuse any drug application if:

a. "he has insufficient information to determine whether such drug is safe for use under such conditions;" or

b. "there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof."

[21 U.S.C. § 355(d)(4)-(5)].

33. The FDA is only permitted to consider clinical evidence to be "substantial," and thus satisfy the Food, Drug and Cosmetic Act, if it –

> consist[s] of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

21 U.S.C. § 355(d). Well-controlled clinical investigations measure the subject drug against a control group, which is provided either a placebo or another recognized drug for comparison. Well-controlled clinical investigations are almost always conducted in a "double-blinded" manner, meaning that the tests are designed so that the study participants and the investigators (as well as the sponsor and associated research organizations) do not know whether each participant has been provided the candidate drug or is a member of the control group. Double-blinding is intended to minimize test bias and error that can arise when the participant and/or investigator have knowledge of the assigned treatment.

34. Prior to conducting any clinical research in humans, a sponsor must screen the proposed drug (or biologic) for toxicity with animal studies, and file an Investigational New Drug ("IND") application with the FDA. Although there are technically three types of IND's,

virtually all drugs are developed under the standard development IND (also known as an investigator IND).[1] An IND application includes the following information:

a. animal pharmacology and toxicology studies sufficient to permit an assessment as to whether the product is reasonably safe for initial testing in humans. Any previous experience with the drug in humans (such as use in foreign countries) also must be included.

b. manufacturing information describing the composition, manufacturer, stability, and controls used for manufacturing the drug substance and the drug product. This information is assessed to ensure that the company can adequately produce and supply consistent batches of the drug.

c. clinical protocols and investigator information including sufficient detail regarding the proposed protocols for clinical studies to assess whether the initial-phase trials will expose human subjects to unnecessary risks.

The sponsor must also commit to obtain informed consent from the research subjects, to obtain review of the study by an institutional review board (IRB), and to adhere to the investigational new drug regulations. 21 C.F.R. § 312.23. After filing an IND, the sponsor must wait 30 days before commencing human clinical trials.

35. The sponsor, and not the FDA, is responsible for determining the design of clinical trials and the protocols for each trial. If a sponsor wants the FDA to agree to the sufficiency of a particular protocol, the sponsor may request a Special Protocol Assessment pursuant to 21 U.S.C. §355(b)(5)(C). Under this provision, the FDA and sponsor meet to discuss the sponsor's proposed protocols, and reduce any agreements to writings that are part of the administrative record and may not be changed except by agreement or under exceptional medical or scientific circumstances. *Id.* Antares did not apply for, and did not receive, any Special Protocol Assessments in connection with its clinical testing of Xyosted.

[1] The other two types of INDs are treatment INDs, for experimental drugs showing promise in clinical testing for serious or immediately life-threatening conditions while the final clinical work is conducted and the FDA review takes place, and emergency use INDs, for experimental drugs in emergency situations that do not allow time for submission of an IND under standard procedures.

36. For each clinical trial, the sponsor also develops a statistical analysis plan ("SAP"). The SAP specifies the statistical techniques that will be used to analyze the data gathered in the study. The SAP is often included in the study protocol; at other times it is a separate document. However, to avoid bias and data-mining, the SAP should be finalized for all well-controlled trials before the study data is unblinded.

37. The success or failure of a clinical trial is measured principally by whether the trial meets pre-specified endpoints, and by the statistical significance of its results.

38. A sponsor generally conducts clinical trials in three phases. These phases, which are codified in FDA regulations, are as follows:

a. Phase 1. Phase 1 studies "are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness."

b. Phase 2. Phase 2 studies are "typically well controlled" studies "conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug."

c. Phase 3. Phase 3 studies are expanded studies "performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 studies usually include from several hundred to several thousand subjects." [21 C.F.R. § 312.21.]

39. The FDA encourages sponsors to meet with it for guidance regarding study design and the NDA process. Dr. Richard A. Guarino, an expert on the NDA process and author of the leading guidebook on the topic, "New Drug Approval Process, Fifth Edition" (CRC Press 2009), explains:

> In addition to meetings before the first human trials begin, the FDA encourages sponsors to meet with it at two critical junctures of the development process:

(a) *End of Phase 2 meeting:* At the end of Phase 2 and before a sponsor begins the extensive and expensive studies in their Phase 3 program, this meeting will discuss the outcome of Phase 2, the protocols to be used in the clinical studies and the plan to conduct the Phase 3 program. At this meeting, the FDA is very precise in what they will expect to see when the sponsor submits the data from the clinical research from the Phase 3 studies that will comprise the main part of the clinical section of the NDA.

(b) *Pre-NDA meeting:* This is generally the most important meeting in the NDA process, because the sponsor provides the FDA a synopsis of the clinical data it intends to submit on the NDA and the FDA provides the sponsor direct feedback on that data. At this meeting, the sponsor may be requested to do additional research before submitting their NDA. These requests are not legal requirements as the FDA does not have the authority to legally require a sponsor to conduct a study. However, defying an FDA request to conduct an additional study has detrimental consequences as the FDA will ultimately determine whether or not to approve the drug.[2]

40. The sponsor chooses which of its officers, employees and consultants attend meetings with the FDA. There is no limit to the number of persons a sponsor may send. Dr. Guarino explains: "Having consulted with many companies going through the NDA process, in my experience, the chief executive officer/president of a development stage company will more likely than not personally attend a pre-NDA meeting involving the company's lead drug candidate, and the chief medical/scientific officer will almost always personally attend a pre-NDA meeting involving a lead drug candidate."

[2] Dr. Guarino was retained by Plaintiff provide background information on the NDA process at the FDA. Dr. Guarino has over 40 years of industry experience. Dr. Guarino has served as Director of Clinical Research at Sandoz Pharmaceuticals, Inc. (now Novartis) and Medical Director at USV Pharmaceuticals (later called Revlon Healthcare). For more than thirty years, he has consulted with numerous pharmaceutical companies of all sizes regarding clinical research, FDA regulatory process, and other related topics. He has been an Associate Professor at Farleigh Dickinson University, served as Director of Medical Education and Director of IND/NDA courses for pharmaceutical industry continuing education firms, and guest lectured on topics regarding clinical research and regulatory compliance at institutions and universities around the world.

41. Pre-NDA meetings and End-of-Phase 2 meetings are formal procedures governed by regulation. They are preceded by briefing books and followed by meeting minutes. As Dr. Guarino explains, "promptly after meeting with the FDA, it is standard practice for the sponsor's attendees and consultants, together with any executives involved in the development program who did not personally attend the meeting, to discuss what transpired at the meeting and to draft the sponsor's version of the minutes. Sponsor's minutes are transmitted to the FDA shortly after the meeting so that the sponsor's version of what transpired can be considered by the FDA when the FDA prepares its official minutes, and any discrepancies can be discussed. The FDA minutes are then circulated to the sponsor. They serve as the official record of the meeting and any agreements reached in the meeting."

42. When a sponsor believes it has conducted sufficient well-controlled clinical trials, and believes that those trials demonstrate substantial evidence of efficacy and safety consistent with the Food, Drug and Cosmetic Act, the sponsor may prepare and file a New Drug Application ("NDA")[3] with the FDA seeking approval for the marketing of the subject drug. The FDA never approves a drug for general use and NDAs, accordingly, do not seek approval for general use. Instead, NDAs seek and the FDA, when presented with scientific evidence meeting the statutory criteria for approval, grants approval for the sponsor to market the subject drug in a specific dose for the treatment of a specific condition or "indication," manufactured pursuant to a specific method, and packaged with a specific label.

43. Within 60 days of receiving an NDA, the FDA will accept the NDA for filing if it believes the NDA is sufficiently complete to permit a substantive review of the information

[3] Or, in the case of a biologic molecule or tissue, a Biologics Licensing Application ("BLA"). This case involves Xyosted, a pharmaceutical drug candidate. Accordingly, it does not involve a BLA.

contained within the NDA. The acceptance of an NDA for filing is not a substantive determination of the merits of the NDA but rather a threshold determination of whether there is enough data to conduct the substantive examination. If the FDA determines that there is a facial problem preventing a meaningful substantive examination – for example, if the NDA is missing paperwork, fails to include data in the proper format, or suffers from other facial errors that make review impossible – the FDA may refuse to file the NDA.

44. The filing of an NDA triggers review deadlines specified in the Prescription Drug User Fee Act ("PDUFA"). The date by which the FDA must issue its response is frequently referred to as a drug's "PDUFA date."

45. An NDA accepted for filing is reviewed for substance by the FDA's Center for Drug Evaluation & Research ("CDER"). Prior to the PDUFA date, CDER may (or may not) convene an advisory committee to provide it with technical advice, enhance its decision-making process, and provide a forum for public discussion of controversial issues.

46. Critically, an advisory committee is the only forum in which the public can legally be advised by the FDA of the FDA's position and the FDA's interactions with the sponsor regarding the drug candidate. Except in advisory committee briefing documents and during the advisory committee hearing, FDA secrecy regulations strictly prohibit the agency from disclosing information regarding pending NDA's. As a result, without an advisory committee, the FDA may not publicly refute a sponsor's misrepresentations regarding clinical trials, protocols, or the sponsor's interactions with the FDA. *See* 21 C.F.R. § 314.430.

47. If the FDA approves the drug candidate, either outright or subject to certain post-approval conditions, it will issue an approval letter in writing to the sponsor. If the FDA finds that the NDA fails to provide the substantial evidence of efficacy and safety required by statute,

or has other material shortcomings which prevent approval, the FDA will send the sponsor a Complete Response Letter, or "CRL", identifying the reasons why the application was not approved. A CRL may, but need not always, request that the sponsor conduct additional clinical trials.

48. CRLs are never made public by the FDA at the time they are issued (although the agency will sometimes release the CRL's in redacted form years later, after the drug candidate is approved or officially abandoned). Accordingly, investors must rely on sponsor companies to provide accurate information regarding CRLs, which can have a devastating effect on a small company's share value.

49. A sponsor may continue to pursue approval of a drug candidate after receiving a CRL by resubmitting its NDA within a specified time period, as extended. An NDA resubmission is also called the sponsor's "complete response" to the CRL because it is supposed to respond to all of the deficiencies identified in the CRL and the sponsor is supposed to indicate on the cover page of the resubmission that it does so. Within 14 days after filing, a resubmission is classified either as a class 1 resubmission or a class 2 resubmission, depending upon its content, and assigned a new PDUFA date.

b. <u>The FDA 505(b)(2) Regulatory Shortcut</u>

50. Established under the Hatch-Waxman Amendments of 1984 to the Federal Food, Drug, and Cosmetic Act, the FDA 505(b)(2) Regulatory Pathway expressly permits the FDA to rely, for approval of NDAs, on data not developed by the applicant.

51. The 505(b)(2) shortcut to approval was intended to motivate innovation without creating duplicate work on what is already known about a drug.

52. In October 1999 by the FDA published the Guidance for Industry, Applications Covered by Section 505(b)(2), in which the agency identified the types of applications that are covered by section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. Below are examples of 505(b)(2) applications:

- New Molecular Entity (NME)
- Change in dosage form
- Change in route of administration
- Substitution of an active ingredient in a combination product
- Formulation change
- Change in active ingredient
- Dosing regimen
- Combination product
- Bioinequivalence
- Change in strength
- Unapproved drug products (DESI)

53. Perhaps the greatest advantage of the 505(b)(2) application is that it is expedited – allowing sponsors to avoid conducting time-consuming and expensive new clinical trials by using previously published studies and prior FDA findings on safety and effectiveness on similar approved drugs. Sponsors of 505(b)(2)s have to pay a user fee under the PDUFA, but in return they get a PDUFA review clock of about 10 months for a standard application and six months for a priority application.[4]

54. While the US 505(b)(2) regulatory pathway allows reduced cost, risk, and time to approval because of the ability to utilize existing data, the publicly available data must be of a standard acceptable to the FDA, with an appropriate bridging strategy and justification to a

[4] Historically, drugs under the FDA's standard 505(b)(1) pathway take as long as 15 years and a nine-figure investment to work their way through the system.

standard acceptable to the FDA. That is, in order to leverage this data, the 505(b)(2) sponsor needs to build a bridge back to the approved product, which may require bioavailability, bioequivalence or efficacy trials, for example, in order to realize the benefits.

55. A recent EP Vantage analysis of publicly-reported CRLs issued by the FDA from January 1, 2017 until May 30, 2018 found that small companies received most of the CRLs issued during this period, of those that were publicly reported.[5]

56. In a joint effort with EP Vantage, Camargo Pharmaceutical Services, a drug development strategist, analyzed the results and discovered another surprising fact: 80% of the CRLs issued for drug products were to companies planning to utilize the 505(b)(2) regulatory pathway for US FDA approval, and all of the 80% were small companies.[6]

Background on TRTs

57. Testosterone levels decline naturally in men as they age over decades. Certain conditions can also lead to abnormally low testosterone levels.

58. Over time, the testicular "machinery" that makes testosterone gradually becomes less effective, and testosterone levels start to fall, by about 1% a year, beginning in the 40s. As men get into their 50s, 60s, and beyond, they may start to have signs and symptoms of low testosterone such as lower sex drive and sense of vitality, erectile dysfunction, decreased energy, reduced muscle mass and bone density, and anemia. Taken together, these signs and symptoms are often called hypogonadism ("hypo" meaning low functioning and "gonadism" referring to the testicles). Researchers estimate that the condition affects anywhere from two to six million men in the United States. Hypogonadism is also commonly referred to as "low testosterone" or, even more colloquially, "Low T."

[5] https://camargopharma.com/2018/06/complete-response-letters-crls/

[6] *Id.*

59. Testosterone as a synthesized steroid was first approved by the FDA in 1939 as the first synthetic steroid.

60. Testosterone enanthate was introduced on the market in the 1950s by Squibb (later Bristol-Myers Squibb). *Enanthate* refers to an organic compound that is introduced to aid in extending release of the testosterone in the blood stream when injected.

61. Due to slow release properties, testosterone enanthate retains relatively high viscous properties, which can make injections difficult and painful. In addition, testosterone ethanate injections have traditionally been administered in medical offices, necessitating an in-person patient visit every two to four weeks.

62. Aside from injections, other TRTs are available, including topical patches and gels. However, patch therapies have experienced extremely high rates of skin irritation, while a significant number of patients have proven unable to absorb gel-based therapies.[7] Additionally, gels carry a high risk of transfer of the drug to spouses and children. Pills are also available for testosterone supplementation, but their use is strongly discouraged because the pill therapies currently available in the United States are known to cause significant liver toxicity.[8]

63. The standard target in TRT is the mid to upper range of normal, which usually means around 500 to 600 ng/dl (nanograms per decilitre).[9] A reading of less than 300 ng/dl is considered indicative of low testosterone in the blood.[10]

64. An auto injector is a device for injecting oneself with a single, preloaded dose of a drug that typically consists of a spring-loaded syringe activated when the device is pushed firmly

[7] *See* https://www.harvardprostateknowledge.org/a-harvard-expert-shares-his-thoughts-on-testosterone-replacement-therapy.
[8] *Id.*
[9] *Id.*
[10] *Id.*

against the body. By simply pressing a button, the syringe needle is automatically inserted and the drug is delivered. By design, auto injectors are easy to use and are intended for self-administration by patients, or administration by untrained personnel. Auto injectors were initially designed to overcome the hesitation associated with self-administration of the needle-based drug delivery device.

65. To administer testosterone enanthate subcutaneously with an auto injector, a highly advanced device is required.

66. The development of the auto injector for testosterone ethanate was intended to improve upon other forms of TRTs like gels and conventional injections, thereby tapping into a $2.3 billion TRT market in the US alone.

Antares Seeks FDA Approval For QST/Xyosted

67. In December 2012, Antares conducted a pre-IND meeting with the FDA as part of preparing to initiate clinical development of QST.

68. In 2013 Antares was granted a patent for an auto-injector, Vibex QuickShot ("QuickShot"), to be utilized in the subcutaneously administration of QST.

69. In July 2014, Antares began a multi-center, Phase 3 clinical study (QST-13-003) evaluating the efficacy and safety of testosterone enanthate administered once-weekly by subcutaneous injection using the QuickShot auto injector in testosterone deficient adult males.

70. In Antares's QST-13-003 study, 150 adult males with low testosterone and testosterone blood levels less than 300 ng/dL (nanograms per decilitre) received a starting dose of 75 mg of QST once weekly for six weeks. Blinded adjustments to dose were made when necessary at week seven based upon the week six pre-dose blood level, and full pharmacokinetic

(PK)[11] profiles were obtained during the twelfth week of treatment. The primary endpoint was the percentage of patients achieving an an average serum total testosterone concentration of 300 to 1,100 ng/dL.

71. On November 3, 2014, Antares announced that the last patient had been enrolled in QST-13-003.

72. On February 25, 2015, Antares announced positive top-line pharmacokinetic results that showed that the primary endpoint was achieved in the Company's QST-13-003 clinical study.

73. At some point – not specified by the Company – between the initiation of QST-13-003 in July 2014 and the reporting of top-line results in February 2015, Antares received written recommendations from the FDA related to its clinical development program for QST. The recommendations received were in response to various clinical, chemistry, manufacturing and controls and user study submissions that Antares made through November 2014.

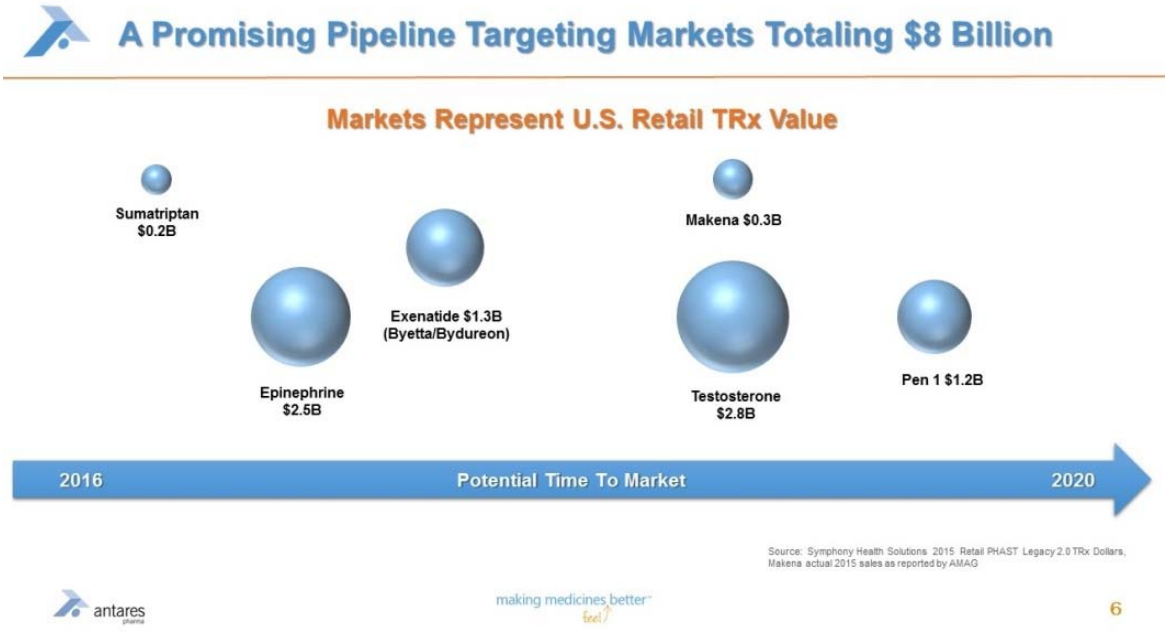
74. According to Antares, based on a single reported occurrence of hives in the Phase 2 study of QST, the FDA recommended that the Company create a larger safety database, including approximately 350 subjects exposed to QST with approximately 200 subjects exposed for six months and approximately 100 subjects exposed for a year.

75. Between June and November 2015, Antares finalized and submitted the protocol for, and enrolled patients in a second Phase 3 study of QST (QST-15-005) pursuant to the FDA's recommendations. The dose-blinded, multiple-dose, concentration-controlled, 26-week QST-15-

[11] Pharmacokinetics ("PK") refers to the activity of drugs in the body over a period of time, including the processes by which drugs are absorbed, distributed in the body, localized in the tissues, and excreted.

005 study included a screening phase, a titration phase and a treatment phase for evaluation of safety and tolerability, including laboratory assessments, adverse events and injection site assessment.

76. At the same time, Antares cited QST as the most lucrative individual component its development pipeline, at $2.8 billion:



77. In the Company's annual report filed with the SEC on March 8, 2016 on Form 10-K, Antares reported on the purported complete results of QST-13-003. Among other things, the Company announced that "there has been one reported death, which was caused by suicide, and …. [t]here was one serious adverse event ("SAE") of hospitalization for worsening depression in a patient with a history of depression."[12]

78. On April 12, 2016, the Company announced that it faced potential delisting by the NASDAQ due to the fact that for 30 consecutive trading days preceding the date of the Notice of Delisting, the bid price of the Company's common stock had closed below the $1.00 per share

[12] *See* https://www.sec.gov/Archives/edgar/data/1016169/000156459016014226/atrs-10k_20151231.htm at 12.

minimum required for continued listing on The NASDAQ Capital Market pursuant to NASDAQ Marketplace Rule 5550(a)(2) (the "Minimum Bid Price Rule").

79. By June 2016, the last patient had completed treatment under QST-15-005, and in September 2016 Antares announced the results of the study. Among the safety population – comprised of 133 patients – it was reported that the most common adverse reactions (incidence ≥5%) were increased hematocrit, upper respiratory tract infection and injection site ecchymosis. Other emergent serious adverse events (SAEs), included one patient with transient visual impairment determined by Antares not to be drug related; one patient with appendicitis that was claimed to not be drug related; one patient with deep vein thrombosis (DVT), which the Company characterized as possibly drug related; and one patient with multiple hospitalizations related to septic arthritis and coronary artery disease, with a complicated clinical course post-angioplasty that the Company deemed not to be drug related.

80. On November 9, 2016, during an earnings call announcing Antares's third quarter (Q3) 2016 results, Defendant Apple stated that the Company had "completed the clinical portion of the phase 3 work" with respect to QST and was "targeting a year-end [NDA] submission."

81. On the Company's May 9, 2017 earnings call, Defendant Apple announced that Defendants had selected the name "Xyosted" for the Company's flagship product. He explained that "[t]he first two letters, X-Y, represents the male chromosome" while "[t]he last four letters S-T-E-D is intended to both reflect the name of our Phase 3 clinical trial, which was named STEADY and to convey the idea that weekly injections of our subcutaneous testosterone was associated with steady physiologically normal levels of testosterone as shown by our PK data collected from our studies."

82. To finance the anticipated launch of Xyosted, management announced in June 2017 that it had secured financing for up to $35 million which carries interest only payments for the next 24 months, after which, it was anticipated, the Company would be profitable.

83. Xyosted was developed under the 505(b)(2) regulatory pathway – discussed above – in which clinical trials had to show that Xyosted does not (or only rarely) result in blood levels of testosterone levels above an upper or below a lower bound during the course of therapy. These levels have been established by the FDA based on experience with numerous other testosterone formulations. As there was no control arm in the QST clinical trials, the comparison between Xyosted, on the one hand, and other TRT drugs, on the other hand, would prove highly relevant with respect to the Xyosted NDA.

84. Unbeknownst to investors, but known at all relevant times within the Company, the incipient Xyosted NDA was facing serious risks in regard to (a) the instance of suicide; and (b) the clinically meaningful increase noted in blood pressure.

85. First, the risk of suicide with Xyosted was far greater than with any other currently marketed TRT.

86. No TRT approved within the last decade recorded a case of completed suicide in the treatment arm of any phase's trial. Xyosted therefore, posed, at minimum, a quantitatively unique safety signal.

87. As the healthcare investment research site *Healthonym* noted following Antares's receipt of the CRL:

> Here's the relevant data on this point; the same kind of data the FDA has required of sponsors in the past.
>
> > A. 0.67% of individuals completed suicide in Xyosted's pivotal trial (1 case; n = 150). If we include the phase 3 safety extension study, this comes out to be 0.35% of participants (n = 283); and 0.27% among all available trial data with

> results (n = 377). Given publicly available information, this is around 447 cases of suicide per 100,000 patient years.
>
> B. 0.00% of 1,999 participants in the pivotal trials used to approve 6 TRTs in the past decade completed suicide. Moreover, even suicide ideation and behavior was practically non-existent.
>
> C. As before, after extending our data to include another 5 European clinical trials and 7 post-marketing studies, 0.02% of participants completed suicide (1 case; n = 5536). An adequate approximation of completed suicides per 100,000 patient years cannot be gleaned from this set of publicly available data.
>
> D. Most men in Xyosted's pivotal trial were 41-66 years old, White, Black, Hispanic, and Asian; observed mainly in 2015. Applying the same criteria to the U.S. population at large, we come to find that 0.03% of all such men in 2015 completed suicide (14,961 cases; n = 51,530,467). This equates to, in a manner of speaking, 29 suicides per 100,000 "patient years".
>
> While D establishes only an approximate comparison given trial exclusion/inclusion criteria, the FDA tends to look at this type of information even if only to get a very general understanding of trends.

Therefore, we can clearly see that **the risk of suicide among the general population (0.03%) closely mirrors that of overall TRT trial data (0.02%), while the risk in either is far smaller than that of Xyosted's (0.27%).** [Emphasis in original.][13]

88. The *Healthonym* article also mined The FDA Adverse Event Reporting System (FAERS) for the following comparative data:

> A. FAERS data tells us that suicides constituted 0.74% of all deaths correlated to any/all TRTs out on the market (5 suicides; 676 deaths).
>
> Suicides comprised 0.04% of adverse event cases (5 suicides; 14,816 adverse event cases).
>
> B. Data from the pivotal, extension, and post-marketing studies on TRTs approved in the past 10 years reveals that suicides constituted 12.5% of all deaths (1 suicide; 8 deaths).
>
> 0.05% of all adversely affected individuals (n = 2,012) completed suicide. Of note: this latter percentage (0.05%) appears to be consistent with approximately equivalent FAERS data (0.04%).

[13] *See* https://healthonym.com/atrs-xyosted-fda-approval/

> C. Available phase 1, 2, and 3 data (n = 377) from Xyosted's trials show us 100% of deaths were as a result of suicide (1 suicide; 1 death).
>
> > 0.46% of individuals experiencing an adverse effect (n = 218) completed suicide.
>
> In summation, what most of this data tends to show is that suicide (quantitatively speaking) poses a serious and unprecedented safety signal for Xyosted with respect to its drug class.
>
> It appears that, **among individuals with adverse events, the risk of suicide is roughly 10 times greater for Xyosted than for any other TRT currently in use.** [Emphasis in original.][14]

89. The *Healthonym* article went on to note that the most recent FDA approval of a drug, not intended for the treatment of psychiatric illness, which posed a unique safety signal with respect to suicide, above and beyond its competitors, involved a candidate with a suicide risk of 0.10% (or equal to 58 suicides per 100,000 patient years) in comparison to Xyosted's 0.27% (or 447 cases of suicide per 100,000 patient years).

90. Critically, these figures were based on the assumption that Antares's revelation of a single suicide was accurate. It was not. In fact, a knowledgeable Company insider confirms that ***two or three suicides***, as opposed to one, occurred. *See* ¶113, below.

91. Second, Xyosted's pivotal trial showed a clear tendency towards a high risk of hypertension.

92. In particular, 12.7% (19 cases; n = 150) of individuals in QST-13-003 and 2.26% of individuals (3 cases; n = 133) in QST-15-005 experienced hypertension; ***7.77%*** between the two trials. This is about 10,161 cases of hypertension per 100,000 patient years.[15]

93. By comparison, among all Phase 3 trial data collected for 6 different TRTs approved in the last ten years, 81 or 4.05% of individuals experienced such an adverse event,

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[14] *Id.*
[15] *Id.*

which works out to approximately 3,564 cases of hypertension per 100,000 patient years among such trials.[16]

94. For European clinical trials and post-marketing studies of TRTs, the risk of hypertension is 1.88%.[17]

95. Accordingly, the *Healthonym* article concluded that "**Xyosted poses, at minimum, a threefold increase in the risk of hypertension when compared to TRT alternatives**" [Emphasis in original.][18]

96. As discussed at ¶¶112, 114-118 below, insiders at Antares knew of the elevated blood pressure risk, yet consciously sought to downplay its significance instead of disclosing the direct link between QST and elevated blood pressure that the FDA would ultimately force the Company to acknowledge.

97. Defendants' denialism occurred in spite of the fact that, in recent years, the FDA has increased the barrier to entry by requesting that sponsors conduct ambulatory blood pressure studies in order to assess for this risk. Antares stated they had conducted such a study pre-CRL, and therefore unquestionably knew the truth about the link between Xyosted and high blood pressure.

Confidential Witness

98. Confidential Witness 1 ("CW1") was the Senior Vice President of Pharmaceutical Development with Antares from November 2013 until January 2017. Based at the Company's headquarters in Ewing, New Jersey, CW1 reported directly to Antares's CEO. Most recently, CW1 reported to the Company's current CEO, Defendant Apple.

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[16] *Id.*

[17] *Id.*

[18] *Id.*

99. CW1 – a Ph.D. in Pharmaceutics from the University of Utah, Salt Lake City – began at Antares in November 2013 after working at Advantar Laboratories as the Executive Vice President and Chief Operating Officer.

100. At Antares, CW1 was responsible for about eight staff members in New Jersey and then twenty-five employees in the Company's Minneapolis, Minnesota office. Device design for products like the auto-injector that was used to administer testosterone was based in Minnesota.

101. Around six months into CW1's tenure with Antares, CW1 was asked to oversee quality assurance and quality control for pharmaceutical development.

102. CW1 oversaw the non-clinical aspect of developing Antares's future product pipeline.

103. Among other things, CW1's team would also evaluate the characteristics of a new drug's active ingredient to see if there was anything obvious that would show the drug to be ineffective.

104. In addition, CW1 would conduct pre-clinical drug evaluations which consisted of testing the drug in animals.

105. Once these processes were complete, CW1 would make early clinical recommendations that met GMP *[Good Manufacturing Practices]* requirements. CW1's team was responsible for producing the clinical trial materials for the Xyosted study.

Xyosted Clinical Trial Oversight

106. The product concept for Xyosted was already in progress when CW1 joined the Company, meaning Antares had a preliminary formulation they wanted to move forward with.

107. Antares's Vice President of Clinical and Medical Affairs, Jonathan S. Jaffe ("Jaffe"), oversaw testing for Xyosted. Jaffe reported directly to Defendant Apple. Jaffe was

responsible for designing and conducted the studies, monitoring them and making decisions based on data collected from them. He also handled any adverse events that occurred during the course of the studies.

108. According to CW1, an adverse event occurs when someone experiences an adverse effect from taking the drug, such as elevated blood pressure or a heart attack. When an adverse event occurred, the investigator working on the trial would contact Antares.

Regular Meetings Were Held Regarding Adverse Events and Clinical Trial Results

109. Staff meetings were held, usually bi-weekly, with the executive team. This included, among others, CW1, Defendant Apple, Defendant Powell, Jaffe, SVP Regulatory Affairs and Quality Assurance Steven Knapp, and the head of pharmacovigilance, Rajesh Thaker.

110. According to CW1, clinical trial results for Xyosted were discussed by the group at these meetings, which were personally moderated by Defendant Apple. Initial results from the pivotal trial, were discussed in order to provide an early read on how things were going.

111. Although they were not finalized, clinical study reports were presented by Jaffe.

112. Early on, in the Xyosted study, over the course of different staff meetings, Jaffe reported that some patients showed an elevation of blood pressure.

113. At the same group meetings early in Xyosted study, there were also updates that ***two or three suicides*** occurred and were being investigated.

114. When the adverse events were brought up, they became a topic for discussion with those in attendance. CW1 stated that the majority of attendees, including Defendant Apple and Jaffe, attempted to justify the adverse events or advance the view that they were not drug related.

115. CW1 recalled pointing out to meeting attendees the significance of a blood pressure rise of 2 millimeters and several suicides in a relatively small study.

116. CW1 stated that when the Xyosted study was finalized, meaning it was checked and confirmed, the high blood pressure and suicide events were confirmed as real observations.

117. CW1 learned from internal discussions at Antares that Defendant COB Jacob was not happy upon hearing of the adverse events and claimed to be surprised.

118. CW1 explained that Defendant Jacob was very concerned about how it would be viewed by the FDA; at this point, the Company scrambled to do an extension study.

Materially False and Misleading Statements Issued During the Class Period

119. The Class Period begins on December 21, 2016, when Antares announced the Company's submission of its NDA for QST to the FDA. In a press release entitled "Antares Pharma Announces Submission of New Drug Application for QuickShot Testosterone," the Company stated, in part:

> "The submission of the QST New Drug Application represents yet another significant accomplishment for the Company in 2016. It is the first product designed for subcutaneous delivery of testosterone through a fine gauge needle in patients diagnosed with hypogonadism," said Robert F. Apple, President and Chief Executive Officer. "We believe QST could be an excellent treatment option for men with hypogonadism. In addition to virtually eliminating the risk of transference that exists with topical gel products and the uncomfortable deep intramuscular administration associated with current injectable therapies, the study data demonstrated that the QuickShot auto injector can provide patients with physiologically normal and steady levels of testosterone over the course of therapy. A potential added benefits to patients is a virtually painless treatment experience as demonstrated by the pain data collected in our phase 3 program. We will work closely with the FDA during the regulatory review process towards a potential approval with the goal of bringing this new treatment option to men diagnosed with hypogonadism."
>
> Two hundred and eighty-three men participated in the QST phase 3 program. The phase 3 program consisted of a one year pivotal safety and efficacy study and a second 6-month safety study. In the phase 3 program, patients received 75 mg of testosterone enanthate (TE) administred via the QuickShot device once-weekly

> for 6 weeks. At week 7, blinded dose adjustments were made if necessary based on week 6 pre-dose blood levels. The patients continued to receive subcutaneous doses of 50 mg, 75 mg or 100 mg of testosterone weekly for up to 52 weeks. The QuickShot testosterone auto injector has not been approved by the United States Food and Drug Administration.

120. The price of Antares shares increased upon the announcement of the QST NDA.

121. The statements referenced in ¶119 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the risk of suicide with Xyosted was far greater than with any other currently marketed TRT; (ii) multiple suicides had occurred during the QST clinical studies, as opposed to the single instance disclosed to investors; (iii) Xyosted's pivotal trial showed a clear tendency towards a high risk of hypertension; (iv) Antares had provided insufficient data to the FDA in connection with its NDA for Xyosted; (v) accordingly, Antares had overstated the approval prospects for Xyosted; and (vi) as a result of the foregoing, Antares' public statements regarding Xyosted were materially false and misleading during the Class Period.

122. On February 27, 2017, Antares issued a press release entitled "Antares Pharma Announces FDA Acceptance of New Drug Application for QuickShot Testosterone." In the press release, the Company stated, in part:

> The FDA has assigned a Prescription Drug User Fee Act (PDUFA) date of October 20, 2017, ten months from the official NDA submission. The PDUFA dates is the target date for the FDA to complete its review of the NDA.
>
> "The FDA's acceptance of the QuickShot testosterone NDA is an important start to the review process and marks another significant milestone for our Company," said Robert F. Apple, President and Chief Executive Officer. "We continue to believe QST could be an excellent treatment option for men with hypogonadism based upon the positive pharmacokinetic and safety data produced in the two phase three studies now on file with the FDA. In addition to virtually eliminating

> the risk of transference that exists with topical gel products and the uncomfortable deep intramuscular administration associated with current injectable therapies, we believe that the phase three studies demonstrated that weekly subcutaneous administration of testosterone using the QuickShot auto injector can provide patients with physiologically normal and steady levels of testosterone over the course of therapy. The study data also showed patients had a virtually painless treatment experience using the device. We will work closely with the FDA during the regulatory review process towards a potential approval."

123. The statements referenced in ¶122 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the risk of suicide with Xyosted was far greater than with any other currently marketed TRT; (ii) multiple suicides had occurred during the QST clinical studies, as opposed to the single instance disclosed to investors; (iii) Xyosted's pivotal trial showed a clear tendency towards a high risk of hypertension; (iv) Antares had provided insufficient data to the FDA in connection with its NDA for Xyosted, and it was misleading for the Company to cite "positive pharmacokinetic and safety data produced in the two phase three studies now on file with the FDA"; (v) accordingly, Antares had overstated the approval prospects for Xyosted; and (vi) as a result of the foregoing, Antares's public statements regarding Xyosted were materially false and misleading during the Class Period.

124. On March 14, 2017, Antares held its Fourth Quarter 2016 Operating and Financial Results Conference Call ("Q4 2016 Conference Call"). During the Q4 2016 Conference Call, Defendant Apple stated, in part:

> Let's start with our most important and exciting asset in development, QuickShot testosterone. 2016 was important year for this product as we set a number of very aggressive deadlines for the completion of the 26- and 52-week Phase 3 PK and safety studies allowing us to move forward and submit an NDA ahead of our original projected filing date of early 2017.

The PK data was extremely impressive and the safety data was consistent with the drug class. We submitted the NDA to the FDA in late December. The NDA was accepted as filed in February and the FDA has assigned an October 20, 2017 PDUFA date. My congratulations to Antares team for an outstanding effort.

125. During the Q4 2016 Conference Call, Defendant Apple further stated that:

…. we closed our 2016 with the submission of a New Drug Application for QuickShot testosterone and now have a PDUFA date in October of 2017. ***Assuming approval, that will mean a late 2017 or early 2018 launch***.

…

Assuming FDA approval, we plan to begin hiring representatives in the fourth quarter of this year in order to successfully launch QST. We've already begun discussions with third party payers to determine pricing and formulary positioning, and key opinion leaders in neurology and endocrinology have expressed enthusiasm for the product ***given the strong PK data and safety profile***. The latest Symphony data shows multi-prescriptions for testosterone products in excess of 500,000, which translates to more than 6 million prescriptions written on an annual basis.

We believe QST has the opportunity to be a first-line therapy for treating testosterone deficiency, ***due to what we believe is potentially best-in-class PK data and patient compliance***. ***We also believe that we can capture share from both the injectable and topical segments of the market, based on our product profile as well as appropriate pricing relative to the market leaders***.

Turning now to slide 11. ***You'll see how impressive the PK data was from the 52-week study***. This graph illustrates the mean testosterone data over the course of 52 weeks of treatment. The chart shows mean testosterone levels well within the acceptable range at the end of the treatment week, prior to the patient's next injection. We believe this is a very compelling dataset, as it shows a steady range of testosterone levels over the extended treatment period.

Slide 12 shows a summary of patient compliance and satisfaction with QST in the 52-week Phase 3 study. With respect to the actual patient injection experience, more than 99% of observed objections were reported as painless. Additionally, a validated Psychosexual Daily Questionnaire was kept by patients and the results over 26-week showed overall improvements in sexual desire, enjoyment, performance, mood, and other related domains.

126. Also during the Q4 2016 Conference Call, Defendant Apple had the following exchange with Jefferies analyst Anthony Petrone:

> **<Q - Anthony Petrone>**: …. And maybe just looking ahead to the cadence of the roll out, I'm just sort of wondering that once your sales force goes out there and it begins to potentially convert patients over, whether they are gel topical or other injectors, it seems to me that I guess it's a once-a-week per patient. And so I'm wondering the extent of initial orders that you could potentially see and sort of who you'll be interfacing with on the other end of that. I'm assuming it would be Cardinal, McKesson, or Bergen.
>
> **<A - Robert F. Apple>**: Yeah. I think that our QST is going to be very similar to OTREXUP in that as a four-pack, so you're going to get a prescription for a month. And we are – I would say, the majority of our sales are going to be through the retail segment. That's where the majority of the market is today. Then the six million prescriptions I mentioned is just the retail segment. There is another segment that exists, which is the testosterone centers that tend to do direct buy and bill and we think there is an opportunity there, but we really don't focus on that when we talk about the opportunity for QST. But I think that for patients, we fully expect that a new patient is going to have to use a generic gel initially just like any product in the market where those generic available, they tend to have to go through those first.
>
> The good news is with the people on gels, they tend to roll-off of gels very quickly. The churn on gels is less than six months. ***So, a patient will be available potentially to QST very quickly and so – but all of our marketing plans, all of our forecasts internally assume that a patient will have to use a generic – some form of generic testosterone before they get to us. But again, I think that we have a very strong value proposition for both the patient and physician with our PK data and the compliance data, and so forth, that we don't anticipate that being a major barrier for us for QST***.

127. The statements referenced in ¶¶124-126 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the risk of suicide with QST was far greater than with any other currently marketed TRT; (ii) multiple suicides had occurred during the QST clinical studies, as opposed to the single instance disclosed to investors; (iii) QST's pivotal trial showed a clear tendency towards a high risk of hypertension; (iv) Antares had provided insufficient data to the FDA in connection with its NDA; (v) accordingly, QST's PK data, "patient compliance," and safety profile was neither

"strong" nor "impressive," and did not offer a "strong value proposition" to doctors or patients given the aforementioned adverse effects of Xyosted; (vi) Antares had overstated the approval prospects for Xyosted, and had no basis to "assume" that approval would be granted; (vii) Defendants' marketing plans did not account for the likelihood of a boxed warning with respect to the aforementioned adverse effects of Xyosted; (viii) as a result of the foregoing, Antares' public statements regarding Xyosted were materially false and misleading during the Class Period.

128. The same day, March 14, 2017, Antares filed an Annual Report on Form 10-K with the SEC, announcing the Company's financial and operating results for the quarter and year ended December 31, 2016 (the "2016 10-K"). In the 2016 10-K, Antares stated, in part:

> We are developing QuickShot® Testosterone ("QST") for testosterone replacement therapy and submitted a 505 (b) (2) New Drug Application ("NDA") with the FDA in December 2016. The NDA submission was accepted for standard review by the FDA and assigned a Prescription Drug User Fee Act ("PDUFA") target date for completion of its review by October 20, 2017. We conducted a multi-center, phase 3 clinical study ("QST-13-003") evaluating the efficacy and safety of testosterone enanthate administered once-weekly by subcutaneous injection using the QuickShot® auto injector in testosterone deficient adult males, and we previously announced positive top-line pharmacokinetic ("PK") results that showed that the primary endpoint was achieved. Based upon a written response we received from the FDA related to our clinical development program for QST, we conducted an additional supplemental safety study, "QST-15-005". The study included a screening phase, a treatment titration phase and a treatment phase for evaluation of safety and tolerability assessments, including laboratory assessments, adverse events and injection site assessments. In September 2016, we announced the successful completion of the QST-15-005 study. The results of these two studies formed the clinical basis of our NDA submission for QST.

129. In the 2016 10-K, Defendants also stated, with respect to QST-13-003, that:

> The most common adverse reactions (incidence ≥5%) in this phase 3 study were increased hematocrit, hypertension, increased prostate-specific antigen, upper respiratory tract infection, sinusitis, injection site bruising and headache. Serious adverse events (SAE's) reported included one case each of worsening depression, vertigo and suicide. None of the SAE's were considered to be related to the study

> drug by the investigators, however the Company determined that the case of suicide could not be ruled out as potentially being related to study drug. There have been no reported adverse events consistent with urticaria (hives), pulmonary oil micro embolism ("POME"), anaphylaxis or major adverse cardiovascular events in this study.

130. The 2016 10-K contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants Apple and Powell, stating that the financial information contained in the 2016 10-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.

131. The 2016 10-K was also signed by Defendant Jacob.

132. The statements referenced in ¶¶128-131 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the risk of suicide with Xyosted was far greater than with any other currently marketed TRT; (ii) multiple suicides had occurred during the QST clinical studies, as opposed to the single instance disclosed to investors; (iii) Xyosted's pivotal trial showed a clear tendency towards a high risk of hypertension; (iv) suicide and hypertension were not merely part of an array of adverse events present among study participants, but were the two most serious adverse events flagged internally even before the FDA asked Antares for additional study data; (v) Antares had provided insufficient data to the FDA in connection with its NDA for Xyosted; (vi) accordingly, Antares had overstated the approval prospects for Xyosted; (vii) Defendants' SOX certifications were false; and (viii) as a result of the foregoing, Antares's public statements regarding Xyosted were materially false and misleading during the Class Period.

133. On April 3, 2017, Antares issued a press release entitled "Antares Pharma Announces Poster Presentation of QuickShot Testosterone Data at the Endocrine Society Annual Meeting." The press release stated, in part:

> The poster, entitled "Safety, Efficacy, and Metabolic Parameters in the STEADY™ Trial of a Novel, Pre-Filled Subcutaneous Testosterone Enanthate Auto-Injector (SCTE-AI)," was authored by Christina Wang, MD, co-principle investigator for the study at Los Angeles Biomedical Research Institute and Harbor-UCLA Medical Center, Los Angeles, CA, et al. The submission was among a select group of key abstracts awarded the distinction of a moderated poster presentation.
>
> The dose-blind, multicenter Subcutaneous Testosterone Efficacy and Safety in Adult Men Diagnosed with Hypogonadism (STEADY™) trial of a proprietary, pre-filled auto injector enrolled 150 hypogonadal adult men with baseline testosterone (T) levels of <300 ng/dL. Patients received 75 mg of testosterone enanthate administered via auto injector once-weekly for six weeks. At week seven blinded dose adjustments were based upon the week six blood concentration levels at the end of the dosing interval (C_{trough}) in the patients. The primary endpoint was the percentage of patients achieving a C_{avg} of 300 to 1,100 ng/dL and a key secondary endpoint was the percentage of patients with week 12 C_{max} testosterone values of <1500 ng/dL. Markers of glucose metabolism (M) and insulin resistance risk (IR) were assessed via the Quantose insulin resistance (IR) panel. Quantose IR and M scores and cholesterol panel assessments were performed from blood samples at weeks 1, 13, 26, 38 and 52.
>
> Of the 150 patients enrolled, 139 patients met the primary endpoint at week 12. Overall, the study found that QuickShot® testosterone (QST) administered to hypogonadal men achieved serum testosterone levels within a clinically desirable and physiologically normal range. Quantose™ IR and M scores suggested a large portion of the patient population exhibited a prediabetic/diabetic phenotype at baseline, and insulin resistance scores were decreased from baseline throughout the treatment period. Total cholesterol, triglycerides, LDL and HDL levels decreased with treatment. ***According to the investigators, QST was found to be safe, well tolerated and virtually pain free***.
>
> "We are pleased that data from our phase 3 QuickShot testosterone study has been accepted for presentation at the annual ENDO 2017 meeting," said Robert F. Apple, CEO of Antares Pharma. Mr. Apple continued, "We believe data compiled to date from our QST clinical program have shown that adult men diagnosed with hypogonadism can achieve a steady pharmacokinetic profile for testosterone well within the physiologically normal range over the course of therapy. We also believe QST has been shown to be well tolerated and virtually painless. We will

> continue to work closely with the FDA during the regulatory review process toward a potential approval."

134. The April 3, 2017 press release further stated that:

> The most common adverse reactions (incidence ≥5%) in the phase 3 study referenced in these presentations were increased hematocrit, hypertension, increased PsA, Upper Respiratory Tract Infection, sinusitis, injection site bruising and headache. ***Serious adverse events reported included one case each of worsening depression, vertigo and suicide. All of the SAE's were not considered to be related to study drug by the investigators, however the Company determined that the case of suicide could not be ruled out as potentially being related to study drug. There have been no reported adverse events consistent with urticaria (hives), POME, anaphylaxis or major adverse cardiovascular events in this study.*** The safety data collected included an assessment of pain. When pain was reported its intensity was recorded using a 10-point pain scale, with a score of 1 described as barely noticeable and 10 as the worst pain experienced. Of 1519 injections assessed, pain was reported 9 times. In these 9 instances, the pain intensity was reported as either a 1 or a 2, with an average score of 1.3. The QuickShot® testosterone auto injector has not been approved by the United States Food and Drug Administration.

135. The statements referenced in ¶¶133-134 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the risk of suicide with Xyosted was far greater than with any other currently marketed TRT; (ii) multiple suicides had occurred during the QST clinical studies, as opposed to the single instance disclosed to investors; (iii) Xyosted's pivotal trial showed a clear tendency towards a high risk of hypertension; (iv) Antares had provided insufficient data to the FDA in connection with its NDA for Xyosted; (v) accordingly, Antares had overstated the approval prospects for Xyosted; and (vi) as a result of the foregoing, Antares's public statements regarding Xyosted were materially false and misleading during the Class Period.

136. On May 9, 2017, Antares issued a press release entitled "Antares Pharma Reports First Quarter 2017 Operating And Financial Results." In the press release, Defendant Apple stated that:

> With the potential for a late 2017 approval of QuickShot testosterone, we will leverage and look to expand our existing commercial organization and infrastructure to support the launch of QST into a large market opportunity which we believe may benefit from a new treatment option," said Robert F. Apple, President and Chief Executive Officer of the Company. "The Company's first quarter results reflect a continued focus on growing product revenue, producing prelaunch quantities of commercial devices and controlling operating expenses with appropriate reinvestment in our future while we await potential FDA approval of four partnered drug device combination products as well as our own QST product.

137. The statements referenced in ¶136 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the risk of suicide with Xyosted was far greater than with any other currently marketed TRT; (ii) multiple suicides had occurred during the QST clinical studies, as opposed to the single instance disclosed to investors; (iii) Xyosted's pivotal trial showed a clear tendency towards a high risk of hypertension; (iv) Antares had provided insufficient data to the FDA in connection with its NDA for Xyosted; (v) accordingly, Antares had overstated the approval prospects for Xyosted; (vi) Xyosted did not present a "large market opportunity" because its elevated hypertension risk ensured that it would be subject to strict labeling, thereby limiting its prescription and sales; and (vii) as a result of the foregoing, Antares' public statements regarding Xyosted were materially false and misleading during the Class Period.

138. Also on May 9, 2017, Antares held its First Quarter 2017 Operating and Financial Results Conference Call ("Q1 2017 Conference Call"). On the Q1 2017 Conference Call, Defendant Apple stated, in part:

> We believe XYOSTED has the potential to be a first line therapy for treating diagnosed testosterone deficiency. We also believe that we can capture share from both the injectable and topical segments of the market based on our product profile and the consistent PK data generated in our Phase 3 study.

139. On the Q1 2017 Conference Call, Defendant Apple had the following exchange with an analyst from Raymond James:

> **<Q>**: Hi, this is [ph] David (22:00) on for Elliot. Thanks for taking the questions. Would you happen to have any updates to share on the regulatory milestones related to the FDA review of QST or I guess, I should say XYOSTED, would you be able to provide any color on items such as the timing of pre-approval inspection or other progress points? Thanks.
>
> **<A - Robert F. Apple>**: Thanks, [ph] David (22:22). We really haven't provided that much update of exactly on where we are with the file, the status, because the FDA, it's kind of a rolling situation where as they go through areas, they might raise questions and so forth. The only thing I can say is that they have, obviously, started the active review of the file. They've gone out to our clinical sites and audited the number of the sites, looked at our analytical labs and we assume that that's done at this point, but on a go forward basis, we're just working with them to pick the PDUFA date of October 20 of this year, ***so I would say nothing unusual at this point in any regards.***

140. The statements referenced in ¶¶138-139 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the risk of suicide with Xyosted was far greater than with any other currently marketed TRT; (ii) multiple suicides had occurred during the QST clinical studies, as opposed to the single instance disclosed to investors; (iii) Xyosted's pivotal trial showed a clear tendency towards a high risk of hypertension; (iv) these adverse effects rendered the Xyosted NDA "unusual" in that

they drastically decreased the likelihood of approval and/or approval without strict regulatory labeling that would negatively impact prescription and sales of Xyosted (v) Antares had provided insufficient data to the FDA in connection with its NDA for Xyosted; (vii) accordingly, Defendants had no basis to believe Xyosted could capture share from both the injectable and topical segments of the market based on product profile and PK data (viii) Antares had overstated the approval prospects for Xyosted; and (ix) as a result of the foregoing, Antares' public statements regarding Xyosted were materially false and misleading during the Class Period.

141. The same day, Antares filed a Quarterly Report on Form 10-Q with the SEC, announcing the Company's financial and operating results for the quarter ended March 31, 2017 (the "Q1 2017 10-Q"). In the Q1 2017 10-Q, Antares stated, in part:

> **Overview of Clinical, Regulatory and Product Development Activities**
>
> We are developing QuickShot Testosterone ("QST") for testosterone replacement therapy, and submitted a 505 (b) (2) New Drug Application ("NDA") to the FDA in December 2016. The NDA submission was accepted for standard review by the FDA and assigned a Prescription Drug User Fee Act ("PDUFA") target date for completion of its review by October 20, 2017. We conducted a multi-center, phase 3 clinical study ("QST-13-003") evaluating the efficacy and safety of testosterone enanthate administered once-weekly by subcutaneous injection using the QuickShot® auto injector in adult males diagnosed with testosterone deficiency, and we previously announced positive top-line pharmacokinetic results that showed that the primary endpoint for this study was achieved. Based upon a written response we received from the FDA related to our clinical development program for QST, we conducted an additional supplemental safety study QST-15-005. The study included a screening phase, a treatment titration phase and a treatment phase for evaluation of safety and tolerability assessments, including laboratory assessments, adverse events and injection site assessments. In September 2016, we announced the successful completion of the QST-15-005 study. The results of these two studies formed the clinical basis of our NDA submission for QST and are further discussed in the "Research and Development Programs" section below.

142. The Q1 2017 10-Q further stated in part, that:

> The most common adverse reactions (incidence ≥5%) in this phase 3 study were increased hematocrit, hypertension, increased prostate-specific antigen, upper respiratory tract infection, sinusitis, injection site bruising and headache. Serious adverse events (SAE's) reported included one case each of worsening depression, vertigo and suicide. None of the SAE's were considered to be related to the study drug by the investigators, however the Company determined that the case of suicide could not be ruled out as potentially being related to study drug. There have been no reported adverse events consistent with urticaria (hives), pulmonary oil micro embolism ("POME"), anaphylaxis or major adverse cardiovascular events in this study.

143. The Q1 2017 10-Q contained signed certifications pursuant to SOX by Defendants Apple and Powell, stating that the financial information contained in the Q1 2017 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

144. The statements referenced in ¶¶141-143 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the risk of suicide with Xyosted was far greater than with any other currently marketed TRT; (ii) multiple suicides had occurred during the QST clinical studies, as opposed to the single instance disclosed to investors; (iii) Xyosted's pivotal trial showed a clear tendency towards a high risk of hypertension; (iv) suicide and hypertension were not merely part of an array of adverse events present among study participants, but were the two most serious adverse events flagged internally even before the FDA asked Antares for additional study data; (v) Antares had provided insufficient data to the FDA in connection with its NDA for Xyosted; (vi) accordingly, Antares had overstated the approval prospects for Xyosted; (vii) Defendants' SOX certifications were false; and (viii) as a result of the foregoing, Antares's public statements regarding Xyosted were materially false and misleading during the Class Period.

145. On August 8, 2017, Antares held its Second Quarter 2017 Operating and Financial Results Conference Call ("Q2 2017 Conference Call"). During the Q2 2016 Conference Call, Defendant Apple stated, in part:

> …. important to our commercial launch plan is the identification of the right physician population for XYOSTED. ***We will be targeting neurologists, primary care physicians and endocrinologists who are currently high prescribers of testosterone products.*** We have completed the physician targeting and we have mapped all the territories for the 60 specialty account representatives which we expect to hire. And as I mentioned earlier, we have already hired seven outstanding regional account managers who will assist in the screening, recruitment and selection of qualified account representatives, as well as the development of all the sales training tools needed for launch.

146. On the same call, Defendant Apple stated that:

> We believe the PK profile of XYOSTED, including both the average T levels after does, as well as the average C trough data, depicts a product that produces clinically meaningful and desirable total testosterone levels. In our Phase 3 trial, 98.5% of study completers were within the physiologically normal range of between 300 nanograms per deciliter and 1,100 nanograms per deciliter six weeks after the start of therapy.
>
> Further, by week 12, patients achieved an average T level of 553 nanograms per deciliter or approximately 330 points above their total testosterone levels prior to treatment. Over the course of one year, the average C trough level for patients in our study was 435 nanograms per deciliter, still well above the cutoff levels considered normal. And importantly, no patients in our study exceeded total T levels of 1,500.
>
> Regarding ease of use and pain associated with self-administration, of 1,519 total injections observed in our Phase 3 study, 1,510 or 99.4% were reported by patients to be completely painless.

147. Defendant Apple further stated on the Q2 2017 Conference Call that, with respect to coverage, "the market still sees testosterone placement as a needed coverage item for patients. And we don't see any trends that are changing in the near term. So we expect good coverage."

148. Defendant Apple also stated, with respect to the Xyosted product launch, that:

> You're going to see a nice steady growth over time, and we haven't given any guidance into what our expectations are for 2018 with regards to launch of XYOSTED. And I think if anyone gives launch guidance, it's kind of – I don't

> know, it seems to be very difficult to do that given that the markets are unpredictable relative to any individual product. And so you get out there and see what the coverage landscape is, and see what type of coverage the other competitive products have. And so, again, I think that we're going to have a nice steady growth of the product ….
>
> ***I think XYOSTED has a lot of benefits for both the patient and physician that – we're not asking the physician to do anything different, we're just – we believe we're just giving them a product that's the best in class***. ***We believe that we're giving them the best way to administer testosterone*** for the patients that are already on testosterone, whether it's an injectable form of testosterone or a gel, they're still trying to basically increase their levels of testosterone by replacing their natural testosterone. ***So we think that with the home – self-administration at home, painless administration for the patients, steady PK, all those product features bode well for the adoption at the doctor level***, as well as the patient level. What we have to then navigate is the payer environment, and we think that we are much better positioned now then we were a few years ago.

149. In regard to doctor prescriptions of Xyosted, Defendant Apple emphasized that "it's really about focusing on those top three or four decile of doctors that will get you the majority of the value of the marketplace."

150. Defendant Apple also had the following exchange with Sameer Kandola of Piper Jaffray:

> **<Q - Sameer Kandola>**: Yeah. This is Sameer on for David. Just a quick one here and may be a follow-up. So how should we think about pricing for XYOSTED and will it be similar to branded gels?
>
> **<A - Robert F. Apple>**: Yeah, so, well, pricing concepts haven't changed dramatically from what I've been saying for the past year or so, the branded products, both AndroGel, which is the market leader, and axiron, which is the number two product in the market, they are around $560 to $570 per month. ***We believe that even though XYOSTED is, in our opinion, better products from – potentially for patients from a compliance and a PK profile and so forth, we intend to actually price it lower than the brands. And the reason is we want to make sure we gain good access for the patients and for the physicians.*** And so we are still in that range of $400 to $500 WACC. So a nice discount or a nice – lower price than the brands, but still a high enough value for us to make it a very meaningful product. Obviously, that's the WACC, and we'll also provide, as I mentioned in our script, rebates and patient support. ***But we think the net selling price for the company and for the patient will still be a very good value for us and a good value for the patient.*** So we are trying to make sure that the uptake and the price is not a barrier to good adoption at launch.

151. In addition, Defendant Apple had the following colloquy with John Vandermosten of Zacks Investment Group:

> **<Q - John D. Vandermosten>**: Good morning. It's John Vandermosten. I had a first question on XYOSTED, and there are a variety of options in the market. I mean, we've talked about them from previous callers. And I wanted to see if you could identify the most attractive patient for this therapy given gels, pills, their upcoming and other injectables that are out there. Who would be the target patient for this? I mean are there any characteristics you think of in terms of that?
>
> **<A - Robert F. Apple>**: John, ***I think that our product, we believe, is a first line product. So anyone who is diagnosed with testosterone deficiency, we believe, is the perfect candidate for XYOSTED.*** It's a once-a-week, at-home administration with a easy to use auto injector. So, we've proven in our human factor studies that patients can easily use the product. It's 99.4% or 99.6% being the painless by the patients that were actually in the Phase 3 studies.
>
> ***So, I think that there isn't any particular patient population that has testosterone deficiency that we're excluding or that we think is a better candidate.*** Whether if you're on a gel today, we believe we can improve the experience of replacing your testosterone by the weekly injection as opposed to a daily application of gel that has transference issues.
>
> And then if you're a patient who is using the generic injectables, it's quite a painful process. We're using a deep IM injection once every two weeks or every three weeks, depending on the brand. But it's very painful, the 19-gauge needle intramuscular in the gluteus. Sometimes done at the doctor's office, sometimes done at home, majority of which are done at the doctor's office.
>
> But you also – what we are providing from a PK standpoint, we believe, is a huge benefit where you don't get these peaks and troughs of your testosterone levels over the course of therapy, which obviously, when a patient has a very high level of testosterone, they feel super physiologic and kind of very energetic. ***And then when they're down for the end of their time, they're typically below the normal range and can feel depressed and really need for a next dose***.
>
> We saw in our study, a very flat PK curve where over an extended period of time, the testosterone levels were very constant. ***And we think that – we believe that will benefit the patient as well. So, overall, it's the whole market. Of those 6 million prescriptions, we believe that our product is appropriate in both the gels and the injectable market***.

152. The statements referenced in ¶¶145-151 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose

material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the risk of suicide with Xyosted was far greater than with any other currently marketed TRT; (ii) multiple suicides had occurred during the QST clinical studies, as opposed to the single instance disclosed to investors; (iii) Xyosted's pivotal trial showed a clear tendency towards a high risk of hypertension; (iv) Antares had provided insufficient data to the FDA in connection with its NDA for Xyosted; (v) due to the aforementioned adverse effects, it was misleading for Defendant Apple to describe Xyosted as "the best way to administer testosterone," "better products," or as "a good value for the patient"; (vi) Antares had overstated the approval prospects for Xyosted, (vii) Defendant Apple's proposal to target specific physician populations – including, but not limited to the "top three or four decile of doctors" – on behalf of Xyosted was misleading because the drug's elevated hypertension risk ensured that it would be subject to strict labeling, thereby limiting its prescription and sales; (viii) for the same reason, Defendant Apple had no basis to expect "good coverage" for Xyosted; (ix) certain classes of patients already suffering from ailments linked to Xyosted – including hypertension, depression, and suicidality – were clearly worse candidates for the drug; and (x) as a result of the foregoing, Antares's public statements regarding Xyosted were materially false and misleading during the Class Period.

153. Also on August 8, 2017, Antares filed a Quarterly Report on Form 10-Q with the SEC, announcing the Company's financial and operating results for the quarter ended June 30, 2017 (the "Q2 2017 10-Q"). In the Q2 2017 10-Q, Antares stated, in part:

> **Overview of Clinical, Regulatory and Product Development Activities**
>
> We are developing XYOSTED (testosterone enanthate) injection for testosterone replacement therapy, and submitted a 505 (b) (2) New Drug

> Application ("NDA") to the FDA in December 2016. The NDA submission was accepted for standard review by the FDA and assigned a Prescription Drug User Fee Act ("PDUFA") target date for completion of its review by October 20, 2017. We conducted a multi-center, phase 3 clinical study ("QST-13-003") evaluating the efficacy and safety of testosterone enanthate administered once-weekly by subcutaneous injection using the QuickShot® auto injector in adult males diagnosed with testosterone deficiency, and we previously announced positive top-line pharmacokinetic results that showed that the primary endpoint for this study was achieved. Based upon a written response we received from the FDA related to our clinical development program for XYOSTED, we conducted an additional supplemental safety study QST-15-005. The study included a screening phase, a treatment titration phase and a treatment phase for evaluation of safety and tolerability assessments, including laboratory assessments, adverse events and injection site assessments. In September 2016, we announced the successful completion of the QST-15-005 study. The results of these two studies formed the clinical basis of our NDA submission for XYOSTED and are further discussed in the "Research and Development Programs" section below.

154. In the Q2 2017 10-Q, Defendants also stated, with respect to QST-13-003, that:

> The most common adverse reactions (incidence ≥5%) in this phase 3 study were increased hematocrit, hypertension, increased prostate-specific antigen, upper respiratory tract infection, sinusitis, injection site bruising and headache. Serious adverse events (SAE's) reported included one case each of worsening depression, vertigo and suicide. None of the SAE's were considered to be related to the study drug by the investigators, however the Company determined that the case of suicide could not be ruled out as potentially being related to study drug. There have been no reported adverse events consistent with urticaria (hives), pulmonary oil micro embolism ("POME"), anaphylaxis or major adverse cardiovascular events in this study.

155. The Q2 2017 10-Q contained signed certifications pursuant to SOX by Defendants Apple and Powell, stating that the financial information contained in the Q2 2017 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

156. The statements referenced in ¶¶153-155 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that:

(i) the risk of suicide with Xyosted was far greater than with any other currently marketed TRT; (ii) multiple suicides had occurred during the QST clinical studies, as opposed to the single instance disclosed to investors; (iii) Xyosted's pivotal trial showed a clear tendency towards a high risk of hypertension; (iv) suicide and hypertension were not merely part of an array of adverse events present among study participants, but were the two most serious adverse events flagged internally even before the FDA asked Antares for additional study data; (v) Antares had provided insufficient data to the FDA in connection with its NDA for Xyosted; (vi) accordingly, Antares had overstated the approval prospects for Xyosted; (vii) Defendants' SOX certifications were false; and (viii) as a result of the foregoing, Antares's public statements regarding Xyosted were materially false and misleading during the Class Period.

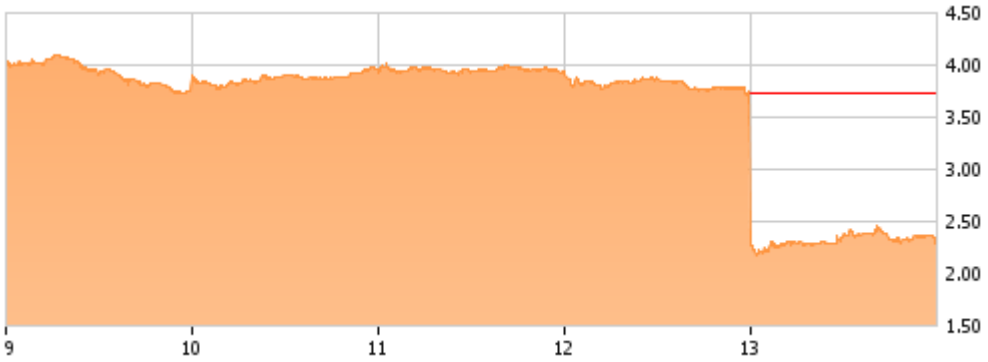
The Truth Emerges

157. On October 12, 2017, after the market had closed, Antares issued a press release entitled "Antares Pharma Provides Xyosted Regulatory Update." In the press release, Antares stated, in part:

> EWING, NJ, October 12, 2017 -- Antares Pharma, Inc. (NASDAQ: ATRS) today announced that, on October 11, 2017, the Company received a letter from the U.S. Food and Drug Administration (FDA) stating that, as part of their ongoing review of the Company's New Drug Application (NDA) for XYOSTED™ (testosterone enanthate) injection, they have identified deficiencies that preclude the continuation of the discussion of labeling and postmarketing requirements/commitments at this time. The letter does not specify the deficiencies identified by the FDA and there has been no further clarification of the deficiencies by the FDA at this time. We anticipate receiving further clarification from the FDA on or before the Prescription Drug User Fee Act (PDUFA) date of October 20, 2017. The Company intends to work with the FDA to understand the nature of the deficiencies once identified and resolve them as quickly as possible.
>
> On December 20, 2016, the Company submitted to the U.S. Food and Drug Administration a New Drug Application pursuant to section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (FDCA), for testosterone enanthate subcutaneous injection. On February 24, 2017, the Company received a letter

from the FDA notifying the Company that the FDA assigned a PDUFA target date for completion of its review by October 20, 2017. On September 22, 2017, the Company received labeling comments from the FDA which the Company responded to on September 29, 2017.

158. On this news, the Company's share price fell $1.41, or 37.80%, to close at $2.32 on October 13, 2017, as illustrated below:



159. On October 20, 2017, following the following the end of the Class Period, Antares issued a press release entitled "Antares Pharma Receives Complete Response Letter From the FDA for XYOSTED." The press release stated, in part:

> EWING, N.J., Oct. 20, 2017 (GLOBE NEWSWIRE) -- Antares Pharma, Inc. (ATRS) announced that today it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for XYOSTED™ (testosterone enanthate) injection. ***The CRL indicates that the FDA cannot approve the NDA in its present form.***
>
> ***The CRL identified two deficiencies related to clinical data***. Based on findings in studies QST-13-003 and QST-15-005, the FDA is concerned that XYOSTED™ could cause a ***clinically meaningful increase in blood pressure***. In addition, the letter also raised a concern regarding the occurrence of ***depression and suicidality***. The CRL did not cite any Chemistry, Manufacturing and Controls (CMC), device or efficacy issues with regard to XYOSTED™. The next step will be to request a meeting with the FDA to further evaluate the deficiencies raised and to agree upon a path forward for a potential approval of XYOSTED™.
>
> "We are disappointed with the outcome of the review and are assessing the content of the Complete Response Letter, including the information that may be needed to resolve the deficiencies," said Robert F. Apple, President and Chief Executive Officer. "The Company remains committed to bringing XYOSTED to

> market and will work closely with the FDA to determine the appropriate responses to the deficiencies noted in the letter." [Emphases added.]

160. From October 12, 2017 through November 8, 2017, Antares common stock declined from a high of $4.09 per share to a low of $1.58 per share.

161. On April 5, 2018, Antares announced that the FDA had acknowledged receipt of the Company's March 29, 2018 resubmission to the CRL received in connection with the Xyosted NDA. The FDA considered this resubmission a complete, class 2 response and assigned a PDUFA of September 29, 2018.

162. On October 1, 2018, Antares announced that it had received FDA approval for Xyosted, but required a black box warning addressing the FDA's concerns cited back in October 2017:

- **XYOSTED™ can cause blood pressure increases that can increase the risk for major adverse cardiovascular events (MACE), including non-fatal myocardial infarction, non-fatal stroke and cardiovascular death, with greater risk for MACE in patients with cardiovascular risk factors or established cardiovascular disease.**
- **Before initiating XYOSTED™, consider the patient's baseline cardiovascular risk and ensure blood pressure is adequately controlled.**
- **Starting approximately 6 weeks after initiating therapy, periodically monitor for and treat new-onset hypertension or exacerbations of pre-existing hypertension in patients on XYOSTED™.**
- **Re-evaluate whether the benefits of XYOSTED™ outweigh its risks in patients who develop cardiovascular risk factors or cardiovascular disease while on treatment.**
- **Due to this risk, use XYOSTED™ only for the treatment of men with hypogonadal conditions associated with structural or genetic etiologies.**

163. The approval also required a separate section under "WARNINGS AND PRECAUTIONS" to address the risk of depression and suicide associated with Xyosted revealed in October 2017:

> **Risk of Depression and Suicide—**Depression and suicidal ideation and behavior, including completed suicide, have occurred during clinical trials in patients treated with XYOSTED™. Advise patients and caregivers to seek medical attention for manifestations of suicidal ideation or behavior, new onset or worsening depression, anxiety, or other mood changes.

164. The pharma industry blog *FiercePharma* cautioned that "Antares can start touting its once-weekly drug's ease of use—Xyosted is an at-home self-injection, while AndroGel is a daily rub-on product—but will also have to contend with a black-box warning detailing risks of blood pressure increases that can lead to serious cardiovascular problems."[19]

165. Black box warnings are the strictest labeling requirements that the FDA can mandate for prescription drugs. First implemented in 1979, black box warnings highlight serious and sometimes life-threatening adverse drug reactions within the labeling of prescription drug products.

166. Investor resource site *The Motley Fool* explains that –

> The Food and Drug Administration gives "black box" warnings to prescription drugs with side effects that can lead to serious injury or death. Officially termed a "boxed warning" by the agency, they're displayed in the upper left of the full prescribing information section of the drug's label.
>
> Drugs with such a label are banned from what the FDA considers "reminder ads" -- the type that display the name of the drug but don't include a list of side effects. Advertising limitations are just one effect a black-box warning can have on a drug's commercial potential.
>
> For some indications, black-box warnings can severely limit a new drug's chances of a successful commercial launch. For example, MannKind's Afrezza began with a black-box warning that required physicians to perform a detailed medical history, physical examination, and lung-strength test before prescribing the inhalable insulin product. With plenty of available options for diabetics that don't require jumping through these hoops, Afrezza's initial launch was a flop.[20]

167. The black box warning for Xyosted is of particular concern because the Company took on debt to finance the development of the drug (*see* ¶82 above) and because, as a writer on

[19] https://www.fiercepharma.com/pharma/aiming-for-abbvie-s-androgel-antares-scores-fda-nod-for-testosterone-drug-xyosted

[20] *See* https://www.fool.com/knowledge-center/what-does-it-mean-for-a-drug-label-to-have-a-black.aspx

Seeking Alpha noted, "[t]he company has never turned a profit, and until recently, has never even had a substantial product revenue stream."[21]

168. As a direct result of the black box and suicide warnings, the price of Antares stock – trading 6.4 million shares – ranged from a high of $3.64 (near the open) to a low of $3.21 (nearly a 12% swing), closing the day near the low at $3.26, a 3% drop from the previous day's close of $3.36:

PLAINTIFF'S CLASS ACTION ALLEGATIONS

169. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or

[21] *See* https://seekingalpha.com/article/4111040-antares-numerous-upcoming-catalysts

otherwise acquired Antares securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures and/or materialization of the risks. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

170. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Antares securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Antares or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

171. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

172. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

173. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;

- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Antares;

- whether the Individual Defendants caused Antares to issue false and misleading financial statements during the Class Period;

- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

- whether the prices of Antares securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

174. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

175. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

- the omissions and misrepresentations were material;

- Antares securities are traded in an efficient market;

- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;

- the Company traded on the NASDAQ and was covered by multiple analysts;

- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

- Plaintiff and members of the Class purchased, acquired and/or sold Antares securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

176. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

177. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

178. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

179. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

180. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to

defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Antares securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Antares securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

181. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Antares securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Antares's finances and business prospects.

182. By virtue of their positions at Antares, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

183. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Antares, the Individual Defendants had knowledge of the details of Antares's internal affairs.

184. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Antares. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Antares's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Antares securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Antares's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Antares securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

185. During the Class Period, Antares securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Antares securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or

otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Antares securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Antares securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

186. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

187. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure and/or materialization of the risk that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against The Individual Defendants)

188. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

189. During the Class Period, the Individual Defendants participated in the operation and management of Antares, and conducted and participated, directly and indirectly, in the conduct of Antares's business affairs. Because of their senior positions, they knew the adverse non-public information about Antares's misstatement of income and expenses and false financial statements.

190. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Antares's financial condition and results of operations, and to correct promptly any public statements issued by Antares which had become materially false or misleading.

191. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Antares disseminated in the marketplace during the Class Period concerning Antares's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Antares to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Antares within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Antares securities.

192. Each of the Individual Defendants, therefore, acted as a controlling person of Antares. By reason of their senior management positions and/or being directors of Antares, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Antares to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Antares and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

193. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Antares.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

LITE DEPALMA GREENBERG, LLC

Dated: October 9, 2018

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